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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,925	01/29/2002	Kevin R. Heath	BSI-491US	9741

7590

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,925

Applicant(s)

HEATH ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-38 and 44-63 is/are pending in the application.
4a) Of the above claim(s) 26-38 and 44-63 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5 and 7-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 7-11, 13-22 24, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,795,439 to Guest in view of US 4,681,570 to Dalton. Guest discloses a catheter with septums that divide the catheter into two or more lumens, with openings in the sidewall for each lumen. The lumens wind helically around the interior of the catheter in order to prevent an entire lumen from being occluded when deployed against a vessel wall. Guest fails to disclose that the catheter itself is formed in a corkscrew or spiral shape. Dalton discloses a corkscrew shaped catheter with several openings in the sidewall that are arranged on the inside and outside of the helix, and may be considered a helical pattern. The catheter, formed of a suitable biocompatible thermoformable elastomer, is about 0.5cm in diameter, with a helix diameter of about 1.0 cm that ends with the catheter pointed in an axial direction. See FIG 1, column 3. It would have been obvious to one of ordinary skill in the art to provide the multilumen catheter disclosed by Guest with a corkscrew-shaped configuration, as disclosed by Dalton, in order to prevent occlusion of an entire segment of the catheter if it's clogged by tissue growth, as taught by Dalton. In the alternative, the Guest device may be

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formed in a corkscrew shape in order to provide stability and support to the vessel in which it's deployed, as taught by US 4,813,925 to Anderson, Jr., et al. With regard to the direction in which the catheter points at its distal end, absent any showing of criticality, the direction of the distal tip is a matter of obvious design choice that is addressed by the prior art cited above.

3. Claims 12 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,681,570 to Dalton in view of US 4,795,439 to Guest, further in view of US 5,190,520 to Fenton, Jr. et al. Dalton and Guest disclose the catheter as claimed with the exception of one lumen extending farther than another and the reinforcing structure. Fenton illustrates that one lumen extends farther than the other in the distal end of the catheter. The catheter further comprises a reinforcing structure as one of the layers in its construction. This configuration aids more efficient and collapse-resistant fluid transfer. See FIG 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a reinforcing structure and a formed tip on the catheter in order to more efficiently transport blood and prevent catheter collapse, as taught by Fenton.

Response to Arguments

4. Applicant's arguments filed 8 June 2005 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the

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claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Guest specifically discloses a reason for his lumen-corkscrew configuration, and Anderson and Dalton provide a reason for forming the catheter itself in a corkscrew shape. Those two disclosures combine to form independent motivation for combining the features of each catheter to form a better catheter.

5. In response to applicant's argument that the references fail to disclose a "hemodialysis catheter," a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use (for example, as specifically disclosed by Dalton), then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

6. With regard to applicant's argument that the Fenton reference does not disclose one lumen extending further than another, FIG 1 of the reference clearly shows that one side of the catheter, equipped with a lumen, extends farther than the other side.

Whether this formation occurs from an extension of the divider is irrelevant—the end of

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one lumen extends beyond the end of a second lumen, as claimed by applicant.

Therefore, the instant invention is unpatentable over the claimed references.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ltd
1 August 2005

Patricia Blanco
PRIMARY EXAMINER
PATRICIA BLANCO
8/1/05